

Remarks

Claims 12-23 and 27-36 are pending upon entry of the foregoing amendments.

Amendments to the Claims

Upon final entry of the previous restriction and species election requirement, claims 1-11 and 24-26 were withdrawn as being drawn to a nonelected species. Applicants hereby cancel claims 1-11 for later inclusion in a divisional application. Applicants respectfully submit that rejoinder of claims 24-26 may be appropriate once a common technical feature is determined to be patentable.

Claims 12-15 and 18-26 currently are amended. Claim 12 has been amended to no longer read on a cancelled claim and to specify the process for preparing the de-esterified pectin and amidated pectin. Support for this amendment may be found throughout the Specification and original claims, including original claims 1 and 10. Claim 12 also has been amended to further specify that the de-esterified pectin is a high molecular weight pectin. Support for this element may be found throughout the Specification, including paragraph [0043] which provides that “a pectin extract is first de-esterified using a biocatalyst ... the resulting high molecular weight de-esterified pectin is further de-esterified and optionally amidated using conventional methods.”

Claims 13-15 and 18-20 have been amended to correct obvious typographical errors and to more concisely reflect the claimed invention in light of the previous withdrawal of the process claims.

Claims 21-26 have been amended to describe end products comprising the amidated pectin. Support for these amendments may be found throughout the Specification, including at paragraphs [0075]-[0080].

New claims 27-36 also are presented herewith. Claim 27 describes an embodiment wherein the high molecular weight de-esterified pectin is characterized by the ratio, R, of molecular weight of the starting pectin material to the molecular weight of the de-esterified pectin. Support for this claim may be found throughout the Specification, including paragraph [0269] which provides that “biocatalyst deesterification resulted in an increase to only as high as 1.15.” Claims 28-36 describe embodiments of the amidated pectin. Support for these claims may be found throughout the Specification and original claims, including claims 12-20.

Rejection Under 35 U.S.C. § 112/101

Claims 21-23 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 21-23 also were rejected under 35 U.S.C. § 101 as being an improper definition of a process. The rejection is respectfully traversed. Applicants respectfully submit that the rejections are moot in light of the claim amendments.

Rejection Under 35 U.S.C. §103

Claims 12-23 were rejected under 35 U.S.C. § 103(a) as being obvious over International Publication WO 99/37685 to Marr et al. (hereinafter “Marr”) in view of International Publication WO 98/58968 to Larsen et al. (hereinafter “Larsen”). The rejection is respectfully traversed.

The Claimed Invention

The presently claimed invention generally is directed to amidated pectins having a low degree of esterification. Conventional methods for de-esterifying and amidating pectins often result in depolymerization and conformational changes of the pectin – leading to problems with solubility and aggregation. (Paragraphs [0033]-[0037] and [0056]). Applicants have discovered that “by first using biocatalytic (e.g., enzymatic) de-esterification, the depolymerization and aggregation during a subsequent chemical de-esterification and optionally amidation are greatly reduced.” (Paragraph [0057]). This allows for the production of “amidated pectins with hitherto unknown low tendency towards aggregation and simultaneously unknown high molecular weight.” (*Id.*).

Because the “Intrinsic viscosity of a pectin is influenced by both the degree of aggregation and the molecular weight of the pectin,” Applicants have chosen to characterize the claimed amidated pectins by a ratio, R_2 , of the intrinsic viscosity of the de-esterified pectin to the amidated pectin. (Paragraph [0276]). The intrinsic viscosity of a pectin also “is directly related to the gel strengths of gels made with that pectin.” (*Id.*).

The Cited Art

Marr discloses preparation and use of pectin having a molecular weight in the range of 20,000 to 50,000 Daltons and a degree of esterification of less than approximately 20 in paste-like materials. (Abstract). Generally, pectins having a low degree of esterification must have a degree of esterification below approximately 10 in order to be heat stable; however, pectin with a low degree of esterification may have problems dissolving. (Page 2, Lines 8-14). To address the problems associated with the low degree of esterification, Marr teaches reduction of both the

degree of esterification and the molecular weight of the pectin, either of which may be performed enzymatically in any particular order. (Page 2, Lines 16-24; Page 4, Lines 9-30; Page 5, Lines 7-11).

Larsen discloses methods of preparing selected fractions of high-esterified pectin by consecutive extraction, the fractions having improved functional characteristics over bulk-extracted pectin. (Abstract). Larsen further describes preparation of the de-esterified pectin fraction by subjecting a pectin having a degree of esterification of 50% or higher to at least one deesterification treatment step to obtain a pectin fraction in which the degree of esterification is reduced by at least 5% and the degree of amidation is in the range of 0-25. (Page 7, Line 33 – Page 8, Line 14). The de-esterification is performed using treatment under acidic conditions or by initial treatment with an acid and subsequent treatment under basic conditions. (Page 18, Line 27 – Page 19, Line 19).

One Skilled in the Art Would Not Combine the Teachings of Marr and Larsen

The Examiner relies on Marr to teach use of a biocatalyst for de-esterification of a pectin and Larsen to teach the subsequent amidation of the de-esterified pectin, however, the Examiner provides no apparent motivation for why one of ordinary skill in the art would be inclined to combine the teachings of the cited references. (Office Action at Page 3). Applicants respectfully submit that one of ordinary skill in the art would not have been inclined to combine the teachings of Marr and Larsen to obtain the Applicants' claimed invention.

As discussed above, Marr discloses methods for preparing pectins having both a low degree of esterification and a reduced molecular weight. Nowhere does Marr remotely teach or suggest that it would be acceptable or even desirable to simply de-esterify the pectin without also

substantially reducing the molecular weight. On the contrary, Marr actually directly contradicts the teachings and elements of Applicants' claimed invention – providing that the molecular weight of the pectin must be reduced in order to improve the solubility of the pectin. (Page 4, Lines 1-8). Such a teaching appears to be an essential feature of the teachings of Marr and directly contradicts the teachings and elements of Applicants' claimed invention. Marr also does not remotely teach or suggest the desirability of amidating the de-esterified pectin without also substantially reducing the molecular weight.

The Examiner seems to suggest Larsen teaches that the optional de-esterification and amidation “provides for improved functional characteristics.” (Office Action at Page 3). As discussed above, Larsen teaches methods for providing high-ester pectin fractions that have improved properties and performance as compared to bulk-extracted pectin. Larsen further teaches that these pectin fractions optionally may be deesterified and/or amidated to obtain deesterified and amidated pectin fractions. (Page 5, Lines 17-30). It is not the methods of de-esterification and amidation in Larsen that provides improved functional characteristics. Rather, it is the preparation of the high-ester pectin fractions in Larsen that result in improved functional characteristics. Thus, there is no rationale for amidating the bulk de-esterified pectins of Marr because Larsen expressly teaches away from use of bulk-extracted pectin. Instead, Larsen depends on the extraction method and fraction selection to improve the functional characteristics of the pectin.

Even if there were a rationale for combining the methods of Marr and Larsen, Applicants respectfully submit that the disclosures of the references teach away from modifying Marr with the teachings of Larsen. As previously described, Marr discloses methods for de-esterifying a

high-ester pectin to a degree of esterification of less than approximately 20. Larsen, however, describes exposing a high-ester pectin fraction “having a degree of esterification of 50% or higher, to at least one deesterification treatment step ... to obtain a pectin fraction having a degree of esterification (DE) which is reduced by at least 5% relative to that of the high-esterified pectin fraction and a degree of amidation (DA,) which is in the range of 0-25.” (Page 8, Lines 1-14). Thus, one skilled in the art would not be inclined to first biocatalyze the de-esterification of the pectin to the degree set forth in Marr and thereafter amidate the de-esterified pectin as taught by Larsen.

Applicants respectfully submit that a more plausible reading of the combination of Marr and Larsen would provide a method utilizing the high-ester pectin fractions of Larsen and the de-esterification and molecular weight reduction of Marr. Thus, the resulting product would be a de-esterified pectin fraction having both a low degree of esterification and a reduced molecular weight.

The Combination of Marr and Larsen Does Not Teach Applicants’ Claimed Invention

In addition, neither of these references remotely teaches or suggests amidated pectins having the claimed characteristics or methods for preparing such amidated pectins. For example, neither of the cited references remotely teaches or suggests the claimed ratio, R2, of the intrinsic viscosity of the de-esterified pectin to the intrinsic viscosity of the amidated pectin of claims 12-14, the claimed ratio, R, of the molecular weight of the starting pectin to the molecular weight of the de-esterified pectin of claims 12 and 27, or the Mark-Houwink factor of claims 18-20. As set forth in the Specification, both the intrinsic viscosity and Mark-Houwink factor are influenced by the molecular weight of the pectin. (Paragraphs [0087] and [0276]).

Although the Examiner acknowledges this failure, the Examiner suggests that these elements would be expected from the product of the combined teachings of Marr and Larsen. (Office Action at Page 4). However, the Examiner provides no rationale to support the conclusion that the product would necessarily result from the modified method of Marr. (See M.P.E.P. 2163.07(a) (providing that inherency may not be established by probabilities or possibilities)).

On the contrary, as Applicants have provided hereinabove, there is no reason to believe that the claimed ratio of intrinsic viscosities, claimed ratio of molecular weights, or the Mark-Houwink factor would necessarily result from combining the teachings of Marr and Larsen. Instead, it is more likely than not that were one to combine the teachings of Marr and Larsen that they would not identify these same claim elements – for example, instead modifying the extraction process using Larsen to obtain a high-ester pectin fraction as the starting material in Marr to obtain a low ester and low molecular weight pectin fraction. This is particularly true in light of the failure of the references to teach the importance of substantially reducing the loss of molecular weight.

Moreover, Applicants respectfully submit that the presently claimed invention requires more than the piecemeal teaching of methods for pectin de-esterification and amidation. The rejection is based on improper hindsight reconstruction, picking and choosing elements from the prior art, and failing to consider the prior art as a whole. 35 U.S.C. § 103(a) specifically requires that the claimed invention be considered “as a whole,” thereby preventing evaluation of the invention on a piecemeal basis. “This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing

features or principles in a new way to achieve a new result – often the very definition of invention.” (Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004)).

In this case, the Examiner’s rationale for combining bio-catalytic de-esterification and amidation to obtain Applicants’ claimed amidated pectins is nothing more than picking and choosing elements from the prior art without consideration of the prior art as a whole. As discussed hereinabove, not only does the prior art as a whole actually teach away from the combination of Marr and Larsen, but any combination of Marr and Larsen would be more likely to result in a product completely different than the Applicants’ claimed invention.

Secondary Considerations Overcomes the Alleged *Prima Facie* Case of Obviousness

Even if the Examiner had set forth a *prima facie* case of obviousness, Applicants’ surprising and unexpected results are sufficient evidence of secondary considerations to establish the nonobviousness of Applicants’ claimed invention.

Applicants’ surprisingly have discovered that when pectin first undergoes biocatalytic de-esterification and subsequently undergoes further de-esterification and/or amidation using conventional techniques, it greatly reduces depolymerization and aggregation. (Paragraph [0057]). As Applicants clearly set forth in the Specification and Examples, conventional methods of de-esterification and amidation will not provide Applicants’ claimed invention absent an understanding of the importance of avoiding the reduction of molecular weight of the pectin during both the de-esterification and amidation steps and the concomitant effect of any reduction in molecular weight on the intrinsic viscosity and Mark-Houwink factor.

Applicants’ Comparative Example 1 and Example 1 illustrate the difference between conventional de-esterification and biocatalytic de-esterification on the molecular weight of the

de-esterified pectin. For conventional acid de-esterification, the molecular weight of the de-esterified pectins was reduced by 34-49% while for biocatalytic de-esterification the molecular weight of the de-esterified pectins was reduced by only 7-13%. (Paragraphs [00261] and [00267]). Subsequent amidation of the de-esterified pectins of Comparative Example 1 and Example 1 resulted in a 15-54 % reduction in intrinsic viscosity for the conventional de-esterified pectins ($R_2 = 1.15-1.54$) as compared to a 3-18 % reduction in intrinsic viscosity for the biocatalytic de-esterified pectins ($R_2 = 1.03-1.18$). (Paragraphs [00279]-[00281] and [00284]-[00286]).

One skilled in the art would not anticipate such a significant difference in the loss of molecular weight or loss of intrinsic viscosity based on the teachings of Marr and Larsen, particularly in light of Marr's contradictory teachings which underscore the need to reduce the molecular weight of the pectin. Even if the combination of Marr and Larsen were to be found to teach individual elements of the methods taught by Applicants', such a teaching is still insufficient to read upon Applicants' claimed amidated pectins without additional understandings which could only be gained through undue experimentation.

The foregoing reasoning and evidence fully and completely rebuts any *prima facie* case of obviousness allegedly established in the Office Action. The rejection therefore should be withdrawn.

Conclusion

For the foregoing reasons, Applicants respectfully submit that all claims are patentable. Allowance of all claims is respectfully requested. If there are any issues which can be resolved by telephone conference or an Examiner's Amendment, the Examiner is invited to contact the undersigned attorney at 404.853.8012 or elizabeth.lester@sutherland.com.

Respectfully submitted,


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